REMARKS:

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1 through 9 were in this application, claims 1-9 have been cancelled and new claims 10-14 have been added. New claim 10 further clarifies the nature of the applicant's invention by listing the various possible ingredients for each listed component of the inventive composition as well as ranges. Support for these are found in claims 2-7 as originally filed and also be reference to the specification, page 3, lines13-17, support for claims 11 and 12 being found in specification page 3, lines 13-17, and page 4, table 1. The optional ingredients in claim 13 are also found on page 3, lines 10-12. Consequently, no new matter is involved in the presentation of new claims 10-15.

The examiner believed that the Declaration filed under 37CRF 1.132 on January 7, 2003 was insufficient to overcome the rejection of claim 1-9. A new Declaration by the applicant is included herewith which confirms that the results based on the Sinus Magic product are applicable to the applicant's invention in that the Sinus Magic product contains each of the components identified in claim 10 herein in the ranges stated. Further, the applicant has confirmed that the particular combination of components has been successfully used by many individuals who previously suffered from sinus discomfort, and that result was achieved without side effects or discomfort. As to the distinction from the prior art, it is quite irrelevant that individual components of the present composition are listed in the prior art. It is the particular combination which is not found in any of the references and absent a teaching supporting the combination, the examiner is merely speculating that the applicant's invention would be obvious. Further, per the examiner's suggestion, the applicant has provided a comparison of unexpected

results in direct comparison to the closest prior art which is Bryce-Smith which describes a zinc sulfate nasal spray for treating the common cold.

As reported in the Declaration, Dr. Salman prepared two solutions of Bryce-Smith's formula, one containing 0.1% zinc sulfate and another containing 1% zinc sulfate. These solutions caused nasal watery discharge as well as lacramation of the eyes. These side effects were mentioned by Bryce-Smith and are believed to be a reason for there being no use of zinc sulfate in nasal spray or drops now on the market. Dr. Salman also found that the Bryce-Smith formula caused a headache which is believed to be due to irritation of the mucous membrane and blockage of the orifices of the sinuses. Dr. Salman also noted that the amount of alcohol is 30 times the amount of alcohol in the Sinus Magic product, Bryce-Smith contains 30 times the menthol and the amount of zinc sulfate is up to 100 times the amount in the inventive formulation. Thus, both the components and effects are readily distinguishable from the present invention.

Claims 1-9 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for use of the term "comfortable pH". This term has been deleted from the application and the term "near neutral pH" has been substituted therefore, and one skilled in the art would find that quite sufficient to select the appropriate pH values for use in the formulation. Further, the specification provides guidance on page 3, lines 6-8 of the specification and consequently the language chosen is believed to be sufficiently definite for one skilled in the art to understand the metes and bounds of the applicant's invention.

Claims 1, 2 and 4-6 were rejected as being anticipate by Hughes U.S. Patent No. 5,322,689. In view of the cancellation of these claims and the presentation of new claims 10-15, this rejection is believed to have been rendered moot. In particular, Hughes does not disclose the

particular combination of ingredients as described in applicant's claim 10 nor the particular ranges of these components and further, the composition of Hughes cannot be used as a nasal passage cleaning composition. This is not a matter of intended use, rather, this is a structural limitation which defines the properties of the composition and absent these properties, the composition cannot function as a nasal passage cleaning composition. In particular, Hughes is directed to topical material that releases aromatic compounds for inhalation. As is clearly identified in the patent, the Hughes formulation is an oil in water or water in oil emulsion, not a salt water solution as is the present composition. Further, this is an essential characteristic of Hughes as the composition incorporates co-polymers which rapidly de-emulsify on the skin to provide a continuous oil film on the skin and then release of the aromatic actives contained therein. Col. 3, lines 18-22. The deposition of oil in the nasal passage would prevent the Hughes composition from functioning as a nasal passage cleaning composition as it would leave significant residue and there is no teaching, suggestion or inference to lead one to produce the composition of the applicant's invention based on Hughes.

Claims 1-7 were rejected under 35 U.S.C. §103(a) as being obvious over Bryce-Smith by itself or in view of Jones, et al. As the examiner has conceded, Bryce-Smith does not exemplify the solution of the applicant's invention nor does Bryce-Smith teach or suggest a nasal passage cleaning composition as described in the applicant's invention. As confirmed by the Declaration of Dr. Salman, the Bryce-Smith composition, which is designed for treatment of the common cold necessarily incorporates fairly high concentrations of zinc sulfate which render the composition quite uncomfortable for one to use. Bryce-Smith fails to address the preparation of a composition for cleaning the nasal passages which additionally does not create such discomfort yet which is effective in opening the nasal passages. Clearly, Bryce-Smith does not teach or

suggest the particular combination of components nor the components withing the ranges described in applicant's claim 10 and consequently new claims 10-14 are not taught or suggested by Bryce-Smith and therefore are not rendered obvious thereby.

The combination with Jones does not lead one to the applicant's invention, particularly as the compositions are directed to distinctive applications. Bryce-Smith is directed to treating the common cold and Jones directed to treating influenza virus. In any event, there is no teaching, suggestion or incentive for utilizing the particular combination of components used in the applicant's invention nor is there any teaching, suggestion or incentive that would lead one to believe that such a composition could be used for cleaning the nasal passages in the absence of a disease condition. Consequently, as there is no teaching, suggestion or incentive supporting the combination nor for leading one to do as the applicant has done, the present claims are not rendered obvious over the combination of Bryce-Smith with Jones.

Claims 8 and 9 were rejected under 35 U.S.C. §103(a) as being obvious over Bryce-Smith in view of Pan. As discussed above, Bryce-Smith teaches a zinc nasal spray with a substantially higher concentration of zinc which apparently was necessary for treating the common cold. Bryce-Smith does not specify n-acetyl l-cystine or methyl salicylate. Pan, et al is directed to a delivery system for localized administration of medicaments, in particular using a soft confectionary material or a hard confectionary material in the form of a lozenge, the object being to provide localized topical delivery of the material to the throat (see col. 13, lines 46-52). No such delivery system could be used in the nasal passage. In addition, Pan describes in column 3 a long list of various ingredients which can be delivered in accordance with the alleged invention and there is nothing that would lead one to choose among the various components to arrive at the applicant's invention nor is there any disclosure of the preparation of a nasal spray for nasal

passage cleaning. On the other hand, the applicant's invention is directed to cleaning and opening the sinus passages in the absence of a diseased condition to improve breathing and prevent the accumulation of environmental pollutents in the nasal passages. There is no teaching, suggestion or incentive in any of the references cited by the examiner for the applicant's inventive composition, nor for the method of cleaning the nasal passages as is described therein.

Based on the above amendments and remarks favorable consideration and allowance of the application is respectfully requested. However, should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of this application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

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